

IN THE CLAIMS:

Please cancel claim 7, and amend claims 1-6, 8-21 and 24 to read as follows. All claims pending, including those unchanged by the present amendment, are reproduced below for the convenience of the Examiner.

1 ✓ (Currently amended) A homogeneous pharmaceutical composition for
2 topical administration comprising:
3 at least 5% by weight, based on the total weight of the composition, of a
4 piperidinopyrimidine derivative or a pharmaceutically acceptable salt thereof;
5 an acid in an amount to substantially completely solubilise the piperidinopyrimidine
6 derivative or a pharmaceutically acceptable salt thereof, wherein the acid is a
7 mineral acid selected from the group consisting of hydrochloric acid,
8 sulphuric acid, nitric acid, and phosphoric acid, or an organic acid selected
9 from the group consisting of citric acid, acetic acid, succinic acid, maleic acid,
10 benzoic acid, lactic acid and mixtures thereof;
11 a solvent selected from water and/or a lower alcohol; ~~and~~
12 a co-solvent selected from one or more of the group consisting of aromatic and
13 polyhydric alcohols; wherein when the co-solvent includes propylene glycol, it is
14 present in an amount of less than approximately 10% by weight;
15 wherein the final product of the homogeneous pharmaceutical composition is
16 selected from the group consisting of a solution, lotion, ointment, mousse, a
17 foam that breaks with shear, spray, aerosol, shampoo, conditioner, gel,
18 cream and paste.

1 2/ (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the acid is added in an amount sufficient to provide an apparent
3 pH to the composition of approximately 7.0 or less.

1 ③ (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the piperidinopyrimidine derivative or pharmaceutically
3 acceptable salt thereof is present in an amount of from approximately 5 to 25% by weight, based
4 on the total weight of the homogeneous pharmaceutical composition.

1 4. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 3, wherein the piperidinopyrimidine derivative or pharmaceutically
3 acceptable salt thereof is present in an amount of approximately 7.5 to 12% by weight, based on
4 the total weight of the homogeneous pharmaceutical composition.

1 5. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the piperidinopyrimidine derivative or pharmaceutically
3 acceptable salt thereof is minoxidil or a salt thereof.

1 6. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 2, wherein the acid provides to the composition an apparent pH in the range
3 of approximately 5.0 to 7.0.

1 7. (Canceled)

1 8. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim [[7]] 2, wherein the acid includes acetic or lactic acid.

1 9. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the composition includes water and ethanol in a range of
3 approximately 1:1 to 1:3 by volume.

1 10. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the co-solvent includes benzyl alcohol.

1 11. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the composition includes water and benzyl alcohol wherein the

3 benzyl alcohol is in an amount of approximately 40 to 100% by weight based on the total weight
4 of the co-solvent system.

1 12. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the water is present in an amount no greater than approximately
3 60% by weight based on the total weight of the co-solvent system.

1 13. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the co-solvent system includes an alkylene glycol.

1 14. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 13, wherein the alkylene glycol is selected from one or more of the group
3 consisting of glycerol, 1,3-butylene or propylene glycol.

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Cont. 1 15. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the acid is present at a level that provides at least 0.01 Normal
3 acid.

1 16. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the acid is present in an amount equal to or greater than the
3 amount of the piperidinopyrimidine derivative in Normal amounts.

1 17. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, wherein the composition includes water and ethanol in a range of
3 approximately 9:1 to 1:9 by volume.

1 18. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 5, wherein the piperidinopyrimidine derivative or pharmaceutically
3 acceptable salt thereof is a minoxidil salt.

1 19. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 18, wherein the minoxidil salt is minoxidil acetate or minoxidil lactate.

1 20. (Currently amended) A homogeneous pharmaceutical composition
2 according to Claim 1, including
3 approximately 5 to 12% by weight, based on the total weight of the composition, of a
4 minoxidil or a minoxidil acid salt;
5 approximately 88 to 95% by weight of a solvent composition including approximately 10
6 to 70% by weight of ethanol, approximately 2.5 to 85% by weight of benzyl
7 alcohol; and
8 less than 10% by weight, propylene glycol.

1 21. (Currently amended) A method for the treatment of hair loss and related
2 indications in humans, comprising the steps of:
3 providing a homogeneous pharmaceutical composition for topical administration having
4 at least 5% by weight, based on the total weight of the composition, of a
5 piperidinopyrimidine derivative or a pharmaceutically acceptable salt thereof;
6 an acid in an amount to substantially completely solubilise the piperidinopyrimidine
7 derivative or a pharmaceutically acceptable salt thereof, wherein the acid is a
8 mineral acid selected from the group consisting of hydrochloric acid,
9 sulphuric acid, nitric acid, and phosphoric acid, or an organic acid selected
10 from the group consisting of citric acid, acetic acid, succinic acid, maleic acid,
11 benzoic acid, lactic acid and mixtures thereof;
12 a solvent selected from water and/or a lower alcohol; **and**
13 a co-solvent selected from one or more of the group consisting of aromatic and
14 polyhydric alcohols; wherein when the co-solvent includes propylene glycol, it is
15 present in an amount of less than approximately 10% by weight; and
16 applying topically to the human scalp a therapeutically or prophylactically effective
17 amount of the homogeneous pharmaceutical composition.

1 22. (Previously presented) A method according to Claim 21, wherein the
2 piperidinopyrimidine derivative or pharmaceutically acceptable salt thereof is minoxidil or a
3 minoxidil salt.

1 23. (Previously presented) A method according to Claim 22, wherein the
2 minoxidil salt is minoxidil acetate or minoxidil lactate.

1 24. (Currently amended) A method according to Claim 21, wherein the
2 **homogeneous** pharmaceutical composition includes

3 approximately 5 to 12% by weight, based on the total weight of the composition, of a
4 minoxidil or a minoxidil acid salt;

5 approximately 88 to 95% by weight of a solvent composition including approximately 10
6 to 70% by weight of ethanol, approximately 2.5 to 85% by weight of benzyl
7 alcohol; and

8 less than 10% by weight, propylene glycol.

1 25. (Canceled)
